

## DETAILED ACTION

1. In view of Interview Summary mailed 30 May 2007, the Office Action mailed 18 May 2007 addressing response and amendment filed 02 March 2007 is hereby vacated.

### General Informal Matters

2. Applicant's telephonic Status inquiry (See Attached Interview Summary from 02/28/2008) for the instant application is acknowledged and entered. In response to said Status Inquiry an Office Action follows. Examiner regrets any inconvenience to applicant because of the delay resulting from circumstances beyond Examiner's Control.

3. This application contains claims 5-20 drawn to an invention nonelected with traverse in the reply filed on 02 August 2006. A complete reply to the instant final rejection must include cancellation of nonelected claims or other appropriate action (See, 37 C.F.R. §1.144; M.P.E.P. §821.01).

### Withdrawals Based on Applicant's Amendments

4. In view of amendments and remarks filed 02 March 2007 the following rejections in the office action mailed 02 November 2006 are hereby withdrawn.

- Written description, enablement and scope rejection to Claims 1-4, 21 under 35 U.S.C. §112 first paragraph;
- indefiniteness rejection to claims 1-4 and 21 under 35 U.S.C. §112 second paragraph; and
- anticipatory rejections to claims 1-4 and 21 under 35 U.S.C. §102(b) as anticipated by anticipated by Morrow et al. (Biochemistry, 2000, Volume 39, Pages 11657-11666).

### Claims Status

5. Claim 2 has currently been canceled.
6. Claims 22-27 have currently been added;
7. Claims 1, 3 and 21 have currently been amended.
9. Claims 5-20 currently remain withdrawn.
10. Claims 1 and 3-27 are currently pending.
11. Claims 1, 3-4, 21 and newly presented Claims 22-27 are examined on merits.

### Information Disclosure Statement

12. The information disclosure statements (i.e., IDSs) filed 04 May 2007 and 20 February 2008 are entered, have been considered and duly completed PTO Form 1449 are enclosed with this Office Action.

### Objection to Specification - New Matter

13. The amendment to specification filed 02 March 2007 is objected to under 35 U.S.C. §132(a) because comparing the information presented in amended paragraph 0049 of the specification with originally filed paragraph 0049 and Paragraphs 00169 and 00179, the information presented in as currently amended paragraph 00049 does not match with that presented in originally filed paragraphs 00169 and 00179. In remarks presented with the response, a statement is made that the support for amendment to paragraph 0049 is present in originally filed paragraphs 00169 and 00179 See Remarks Lines 8-9). In each of originally filed paragraphs 00169 (See, Lines 3-4) and 00179 (See, Lines 11-14) the information presented for apoE3 and apoE4 respectively is as follows:

apoE Isoform	Maximum (%) Abundance	pH	Urea Concentration (M)
apo E3	80	4.0	4.75
apo E4	90	4.0	3.75

Furthermore, the above presented information regarding apoE4 is confirmed from the data presented in Table at Page 44.

Since from the originally presented paragraph 0049 of the specification, it is not clear what indeed are the correct parameters for the urea concentration to get maximum abundance for each one of apoE3 and apoE4, while the information presented in each of paragraphs 00169 is supportive of each other; it is deemed that maximum abundance for apoE3 in the urea concentration range of 4.5M to 5M and for apoE4 in the urea concentration range of 3.5M-4.5M is erroneous and is construed as new matter.

Based on the foregoing discussion, in the reply to this office action, applicant is requested to cancel the information in amended paragraph 0049 since said information is construed as new matter.

### *Claim Rejections - 35 U.S.C. § 112*

#### *Claim rejections - 35 U.S.C. § 112, 1<sup>st</sup> paragraph written description*

14. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

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*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

15. Based on the amendment filed 02 March 2007, the following is a new rejection under 35 U.S.C. §112, first paragraph.

Newly presented Claims 26-27 are considered new matter on the basis of the discussion presented in item 12 *supra*. Further support for considering Claims 26-27 as new matter comes from the fact that the urea concentration of 3.5M-4.5 M is considered related to the concentration of urea at which maximum abundance for apoE4. The urea concentration for maximum abundance for apoE4 has been determined to be at 3.75 M (See Table above in item 12 and on the basis of the support presented in specification paragraphs 00169 and 00179). Similarly, newly presented Claim 27 is considered to be new matter because it is considered to be related to the urea concentration for maximal abundance for apoE3 said urea concentration has been established to be at 4.75m (See Specification Paragraphs 00169 and 00179 and Table in item 12 above).

***Claim rejections - 35 U.S.C. § 112, Second Paragraph***

16. Based on the amendment filed 02 March 2007, the following is a new rejection under 35 U.S.C. §112, second paragraph.

17. Following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

18. Claims 1, 3-4, 21 and newly presented Claims 22-27 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Recitation, “at least about” renders Claim 1 incomprehensible, unclear and vague. The word “about” in and by itself means “in vicinity of” i.e., a range. The phrase “at least” implicitly also gives a range because of minimum number and maximum number which could be infinite, or in vicinity of which claimed number or parameter should be present. Thus, this is a range in range situation, one range given according to the recitation, “about” and the other according to the phrase, “at least”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the

resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range in range situation is identified because of the recitation "at least" followed by the recitation "about" and then a number (i.e., 80%). The about giving the connotation of a range within the range. Appropriate correction is required.

- Recitation "about 1.0 to about 5.0" in Claim 1 renders said Claim incomprehensible, unclear and vague. The word "about" in and by itself means "in vicinity of" i.e., a range. Additionally, a range of "1.0-5.0" is given. Thus, this is a range in range situation, one range given according to the recitation, "about" and the other according to the phrase, "1.0 to 5.0". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range in range situation is identified because of the recitation "about" followed by the recitation "1.0 to 5.0". The about giving the connotation of a range within the range. Appropriate correction is required.
- Recitation, "from about 2.0 to about 4.0" in Claim 24 renders said Claim incomprehensible, unclear and vague. The word "about" in and by itself means "in vicinity of" i.e., a range. Additionally, a range of 2.0-4.0 is given. Thus, this is a range in range situation, one range given

according to the recitation, "about" and the other according to the phrase, "2.0 to 4.0". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range in range situation is identified because of the recitation "about" followed by the recitation "2.0 to 4.0". The about giving the connotation of a range within the range. Appropriate correction is required.

- Recitation, "from about 2M to about 7M" in Claim 25 renders said Claim incomprehensible, unclear and vague. The word "about" in and by itself means "in vicinity of" i.e., a range. Additionally, a range of "2M to 7M" is given. Thus, this is a range in range situation, one range given according to the recitation, "about" and the other according to the phrase, "2M to 7M". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range in range situation is identified because of the recitation "about" followed by the recitation "2M to 7M". The about giving the connotation of a range within the range. Appropriate correction is required.

- Recitation “from about 3.5M to about 4.5M” in Claim 26 renders said Claim incomprehensible, unclear and vague. The word “about” in and by itself means “in vicinity of” i.e., a range. Additionally, a range of “3.5M-4.5M” is given. Thus, this is a range in range situation, one range given according to the recitation, “about” and the other according to the phrase, ”3.5M to 4.5M”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range in range situation is identified because of the recitation “about” followed by the recitation “3.5M to 4.5M”, The about giving the connotation of a range within the range. Appropriate correction is required.
- Recitation “from about 4.5M to about 5M” in Claim 27 renders said Claim incomprehensible, unclear and vague. The word “about” in and by itself means “in vicinity of” i.e., a range. Additionally, a range of “4.5M to 5M” is given. Thus, this is a range in range situation, one range given according to the recitation, “about” and the other according to the phrase, “4.5M to 5M”. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte*

*Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the range in range situation is identified because of the recitation “about” followed by the recitation “4.5M to 5M”. The about giving the connotation of a range within the range. Appropriate correction is required.

All other claims directly or indirectly depend from the rejected claim 1 and are, therefore, also rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph for the reasons set forth above.

### Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this office action. **Accordingly, this action is made final.** See M.P.E.P. §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for reply to this final action is set to expire three months from the mailing date of this action. in the event a first reply is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the date of this final action.

20. For the aforementioned reasons, no claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 a.m. to 6:00 p.m. (eastern standard or daylight savings time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, dr. Jon Weber, can be reached on (571)-272-0295 Monday through Friday 8:00 a.m. to 4:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the patent application information retrieval (i.e., pair) system. Status information for the published applications may be obtained from either private pair or public pair. Status information for unpublished applications is available through private pair only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the private pair system, contact the electronic business center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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Examiner, Art Unit 1657

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05 March 2008

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